PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	Docket No: Q91836
Mikio AOKI	
Appln. No.: 10/559,661	Group Art Unit: 1635
Confirmation No.: 5101	Examiner: Amy Hudson BOWMAN
Filed: December 5, 2005	

For: METHOD OF NUCLEIC ACID INFUSION

RESPONSE TO RESTRICTION AND ELECTION OF SPECIES REQUIREMENTS

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This responds to the Restriction and Election of Species Requirement, dated November 21, 2007.

Restriction Requirement

In the Office Action, Applicants are required to elect one of the inventions of Groups I-XIV. In response to the Restriction Requirement, Applicants elect Group I, Claims 1-21 and 49 for examination. This election is made with traverse, of which detail discussions are provided below.

Species Election

The Office also has required Applicants, when the invention of Group I is elected, to elect a single species for prosecution on the merits to which the claims shall be restricted.

In response, Applicants elect the following species.

For the oligonucleotide, Applicants elect a double-stranded oligonucleotide.

For the specific backbone and/or sugar modification, Applicants elect a small interfering RNA (siRNA).

For the substance of the hypertonic solution, Applicants elect oligosaccharide.

For the oligosaccharide, Applicants elect sucrose.

The claims that read on the elected species are 1-8 and 49.

Traverse

In the Office Action, it is asserted that the inventions listed as Groups I-XIV do not relate to a single general inventive concept under PCT Rule 13.2 because they lack the same or corresponding special technical features. The Office further asserts that the special technical feature is a method of nucleic acid infusion comprising the steps of (a) bringing a nucleic acid, a hypertonic solution and cells into contact with each other; and (b) lowering the osmotic pressure of the hypertonic solution after step (a). However, according to the Office, this special technical feature is known in the art, as seen for example, in Gopal *et al.* (Mol. Cell Biol., Vol. 5, No. 5, pages 1188-1190 (1985)) ("Gopal"). Therefore, the Office concludes that there is no special technical feature linking the groups listed above.

Applicants respectfully traverse the Restriction Requirement between Groups I-XIV for the following reasons.

Applicants first note that under PCT Rule 13.1, governing unity of invention, an international application must relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Unity of invention exists where there is a technical relationship among the claimed inventions involving one or more special technical features. The term "special technical feature" is defined to mean those technical features that define a contribution which each of the inventions considered as a whole, makes over the prior art.

Applicants respectfully submit that the disclosure of Gopal neither anticipates nor renders obvious the claimed inventions of the present application. Specifically, Gopal teach a gene transfer method containing the steps of attaching cells to a concanavalin A-coated tissue culture dish, treating the cells with DEAE-dextran to absorb plasmid DNA to the attached cells, and treating the cells with PEG to facilitate the uptake of the DNA by the cells.

According to Gopal, since DEAE-dextran is positively charged, a plasmid DNA forms a complex with DEAE-dextran, whereby the DNA can be easily absorbed to the cells, and then the uptake of the DNA by the cells is facilitated with PEG.

On the other hand, the method of the present invention is characterized in that cells and nucleic acids are contacted with a hypertonic solution, and then the osmotic pressure of the hypertonic solution is lowered, whereby the difference in osmotic pressure, namely osmotic

pressure shock causes the nucleic acids to be delivered into the cells. See page 3, line 16 to page 5, line 5 of the specification.

Thus, Applicants submit that the method of the present invention is fundamentally and totally different from the method of Gopal.

Further, Gopal teaches that the DEAE-dextran solution has a concentration of 5 mg/mL, namely 10 μM, as described in page 1188, right column, line 4. This concentration is quite low, and one skilled in the art would understand that the DEAE-dextran solution is therefore not at all a hypertonic solution.

With regard to a hypertonic solution, the specification of the present application states at page 25, line 27 to page 26, line 6, as follows:

> ...it is necessary to prepare the hypertonic solution so that the oligosaccharide and/or the polyhydric alcohol present in the hypertonic solution has a total molarity of 0.29 M to 3 M for allowing the cellular uptake of the nucleic acid when the hypertonic solution, the nucleic acid and the cells are brought into contact with each other.

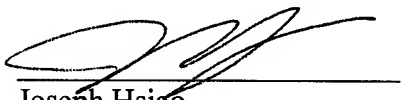
In view of the foregoing, Applicants respectfully submit that the claimed invention is distinguishable over the disclosure of Gopal, and that there exists a special technical feature linking the groups listed in the Office Action.

Applicant submits that if any of the elected claims is found to be allowable, claims dependent therefrom should similarly be considered allowable in the same application.

Applicant reserves the right to file a Divisional Application directed to non-elected claims 22-48 and 50-102.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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